



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-3411-N]

### Medicare, Medicaid, and CLIA Programs; Clinical Laboratory Improvement Amendments of 1988 Exemption of Permit-Holding Laboratories in the State of New York

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** This notice announces that laboratories located in and licensed by the State of New York that possess a valid permit under the New York State Public Health Law are exempt from the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) for a period of 6 years.

**DATES:** The exemption granted by this notice is effective from [insert date of filing for public inspection at OFR] to **March 26, 2027**.

**FOR FURTHER INFORMATION CONTACT:** Penny Keller, (410) 786-2035.

### SUPPLEMENTARY INFORMATION:

#### I. Background and Legislative Authority

Section 353 of the Public Health Service Act (PHSA), as amended by the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Pub. L. 100-578, enacted on October 31, 1988), generally provides that no laboratory may perform tests on human specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or assessment of the health of, human beings unless it has a certificate to perform that category of tests issued by the Secretary of the Department of Health and Human Services (HHS). Under section 1861(s)(17)(A) of the Social Security Act (the Act), the Medicare program will only pay for laboratory services if the laboratory has a CLIA certificate. Section 1902(a)(9)(C) of the Act

generally requires that state Medicaid plans pay only for laboratory services furnished by CLIA-certified laboratories. Thus, although subject to specified exemptions and exceptions, laboratories generally must have a current and valid CLIA certificate to test human specimens for the purposes noted above to be eligible for payment for those tests from the Medicare or Medicaid programs. Regulations implementing section 353 of the PHSA are contained in 42 CFR part 493.

Section 353(p) of the PHSA provides for the exemption of laboratories from CLIA requirements in states that enact legal requirements that are equal to or more stringent than CLIA's statutory and regulatory requirements. Section 353(p) of the PHSA is implemented in subpart E of our regulations at 42 CFR part 493. Sections 493.551 and 493.553 provide that we may exempt from CLIA requirements, for a period not to exceed 6 years, all state-licensed or -approved laboratories in a state if the state licensure program meets the specified conditions. Section 493.559 provides that we will publish a notice in the **Federal Register** when we grant an exemption to an approved state licensure program. It also provides that the notice will include the following:

- The basis for granting the exemption.
- A description of how the state's laboratory requirements are equal to or more stringent than those of CLIA.
- The term of approval, not to exceed 6 years.

#### A. State of New York's Application for CLIA Exemption of Its Laboratories

The State of New York has applied for exemption of its Clinical Laboratory Evaluation Program (CLEP) permit-holding laboratories from CLIA program requirements. New York State law is generally applicable to all clinical laboratories operating within the State of New York except those operated by the Federal Government and those operated by a licensed physician, osteopath, dentist, midwife, nurse practitioner or podiatrist who performs laboratory tests or procedures, personally or through his or her employees, solely as an adjunct to the

treatment of his or her own patients. The State of New York submitted all of the applicable information and attestations required by §§ 493.551, 493.553, and 493.557(b) for state licensure programs seeking exemption of their licensed laboratories from CLIA program requirements. (Please note that although the CLEP issues “permits” rather than “licenses” or “certificates,” for the purposes of this notice, we will hereinafter refer to the CLEP as a “state licensure program.”) Examples of documents and information submitted include a comparison of its laboratory licensure requirements with comparable CLIA condition-level requirements (that is, a crosswalk) and a description of the following: its inspection process; its proficiency testing (PT) monitoring process; its data management and analysis system; its investigative and response procedures for complaints received against laboratories; and its policy regarding announced and unannounced inspections.

#### B. CMS Analysis of New York’s Application and Supporting Documentation

To determine whether we should grant a CLIA exemption to laboratories licensed by a state, we review the application and additional documentation that the state submits to us and conduct a detailed and in-depth comparison of the CLEP state licensure program and CLIA’s statutory and regulatory requirements to determine whether the state program meets the requirements at subpart E of part 493.

In summary, the state generally must demonstrate that:

- It has state laws in effect that provide for a state licensure program that has requirements that are equal to or more stringent than CLIA condition-level requirements for laboratories.
- It has implemented a state licensure program with requirements that are equal to or more stringent than the CLIA condition-level requirements such that a laboratory licensed by the state program would meet the CLIA condition-level requirements if it were inspected against those requirements.
- The requirements under that state licensure program meet or exceed the requirements

of §§ 493.553, 493.555, and 493.557(b) and is suitable for approval by us under § 493.551. For example, among other things, the program would need to:

- ++ Demonstrate that it has enforcement authority and administrative structures and resources adequate to enforce its laboratory requirements.

- ++ Permit us or our agents to inspect laboratories within the state.

- ++ Require laboratories within the state to submit to inspections by us or our agents as a condition of state licensure.

- ++ Agree to pay any costs associated with our activities to validate its state licensure program as well as the state's pro rata share of the general overhead to develop and implement CLIA as specified in §§ 493.645(a), 493.646(b), and 493.557(b).

- ++ Take appropriate enforcement action against laboratories found by us or our agents to be out of compliance with requirements comparable to CLIA condition-level requirements, as specified in § 493.557(b).

As specified in our regulations at §§ 493.555 and 493.557(b), our review of a state licensure program includes (but is not necessarily limited to) an evaluation of the following:

- Whether the state's requirements for laboratories are equal to or more stringent than the CLIA condition-level requirements.

- The state's inspection process requirements to determine the following:

- ++ The comparability of the full inspection and complaint inspection procedures to those of CMS.

- ++ The state's enforcement procedures for laboratories found to be out of compliance with its requirements.

- The ability of the state to provide us with electronic data and reports with the adverse or corrective actions resulting from PT results that constitute unsuccessful participation in CMS-approved PT programs and with other data we determine to be necessary for validation review and assessment of the state's inspection process requirements.

- The state's agreement with us to ensure that the agreement obligates the state to do the following:

- ++ Notify us within 30 days of the action taken against any CLIA-exempt laboratory that has had its licensure or approval withdrawn or revoked or been in any way sanctioned.

- ++ Notify us within 10 days of any deficiency identified in a CLIA-exempt laboratory in cases when the deficiency poses an immediate jeopardy to the laboratory's patients or a hazard to the general public.

- ++ Notify each laboratory licensed by the state under its approved state licensure program within 10 days of a withdrawal of our approval of the state's licensure program, and the resulting loss of the laboratory's exemption from CLIA based on its licensure under that program.

- ++ Provide us with written notification of any changes in the state's licensure (or approval) and inspection requirements.

- ++ Disclose to us or our agent any laboratory's PT results in accordance with the state's confidentiality requirements.

- ++ Take appropriate enforcement action against laboratories that we or our agents find to be out of compliance with CLIA condition-level requirements in a validation survey, and report these enforcement actions to us.

- ++ Notify us of all newly licensed laboratories, and any changes in the specialties and subspecialties for which any laboratory performs testing, within 30 days.

- ++ Provide us, as requested, inspection schedules for validation purposes.

In keeping with the process described above, we evaluated the application and supporting materials that were submitted by the State of New York to verify that CLEP permit-holding laboratories will meet or exceed the requirements of the following subparts of part 493: subpart H, Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing; subpart J, Facility Administration for Nonwaived Testing; subpart K, Quality Systems for Nonwaived

Testing, subpart M, Personnel for Nonwaived Testing; subpart Q, Inspection; and subpart R, Enforcement Procedures.

We found that the State of New York's CLEP requirements mapped to all the CLIA condition-level requirements. Its inspection and proficiency testing monitoring processes were adequate. Other materials that were submitted demonstrated compliance with the other above-referenced requirements of subpart E of part 493. As a result, we concluded that the submitted documents supported exempting CLEP permit-holding laboratories from the CLIA program requirements. Furthermore, a review of our validation inspections conducted by our branch location in New York supported this conclusion.

The Federal validation inspections of CLIA-exempt laboratories, as specified in § 493.563, were conducted on a representative sample basis, as well as in response to any substantial allegations of noncompliance (that is, complaint inspections). The outcome of those validation inspections has been, and will continue to be our principal tool for verifying that the laboratories located within the state that hold valid permits are in compliance with CLIA requirements.

Our branch location in New York has conducted validation inspections of a representative sample (approximately 5 percent) of the laboratories inspected by the New York State Office of Laboratory Quality Assurance (LQA). The validation inspections were primarily of the concurrent type; that is, our surveyors accompanied New York State's inspectors, each inspecting against his or her agency's respective regulations. Analysis of the validation data revealed no significant differences between the State and Federal findings. The validation surveys verified that the State of New York CLEP inspection process covers all CLIA conditions applicable to each laboratory being inspected and also verified that the CLEP requirements meet or exceed CLIA condition-level requirements. Our validation surveys found the State inspectors highly skilled and qualified. The LQA inspected laboratories in a timely fashion; that is, all laboratories were inspected within the required 24-month cycle. All parameters monitored by

our branch location in New York, to date, indicate that the State of New York is meeting all requirements for approval of CLIA exemption. This Federal monitoring will continue as an ongoing process.

### C. Conclusion

Based on review of the documents submitted by the New York State licensure program, CLEP, pursuant to the requirements of subpart E of part 493, as well as the outcome of the validation inspections conducted by our branch location in New York, we find that the State of New York's licensure program meets the requirements of § 493.551(a), and that, as a result, we may exempt from CLIA program requirements all State-licensed or -approved laboratories.

Approval of the CLIA exemption for laboratories located within and permitted by the State of New York is subject to removal if we determine that the outcome of a comparability review or a validation review inspection is not acceptable, as described under §§ 493.573 and 493.575, or if the State of New York fails to pay the required fee every 2 years as required under § 493.646(b).

### D. Laboratory Data

In accordance with our regulations at § 493.557(b)(8), the approval of this exemption for laboratories located within and permitted by the State of New York is conditioned on the State of New York's continued compliance with the assertions made in its application, especially the provision of information to us about changes to a laboratory's specialties or subspecialties based on the State's survey, and changes to a laboratory's certification status, such as a change from a CLIA certificate of compliance to a CLIA certificate of waiver.

### E. Required Administrative Actions

CLIA is a user-fee funded program. The registration fee paid by laboratories is intended to cover the cost of the development and administration of the program. However, when a state's application for exemption is approved, we do not charge a fee to laboratories in the state. The state's share of the costs associated with CLIA must be collected from the state, as specified

in § 493.645(a).

The State of New York must pay for the following:

- Costs of Federal inspections of laboratories in the State to verify that New York State's laboratory licensure program requirements are equivalent to or more stringent than those in the CLIA program, and that they are enforced in an appropriate manner. The average Federal hourly rate is multiplied by the total hours required to perform Federal validation surveys within the State.
- Costs incurred for Federal surveys, including investigations of complaints that are substantiated. We will bill the State of New York on a semiannual basis.
- The State of New York's proportionate share of the costs associated with establishing, maintaining, and improving the CLIA computer system, based on the portion of those services from which the State of New York received direct benefit or which contributed to the CLIA program in the State. Thus, the State of New York is being charged for a portion of our direct and indirect costs of administering the CLIA program. Such costs will be incurred by CMS, the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA) and contractors working on behalf of these respective agencies.

To estimate the State of New York's proportionate share of the general overhead costs to develop and implement CLIA, we determined the ratio of laboratories in the State to the total number of laboratories nationally. Approximately 1.5 percent of the registered laboratories are in the State of New York. We determined that a corresponding percentage of the applicable CMS, CDC, FDA, and their respective contractor costs should be borne by the State of New York.

The State of New York has agreed to pay the State's pro rata share of the anticipated overhead costs and costs of actual validation (including complaint investigation surveys). A final reconciliation for all laboratories and all expenses will be made. We will reimburse the State for any overpayment or bill it for any balance.



## **II. Approval**

In light of the foregoing, we grant approval of the State of New York's laboratory licensure program (CLEP) under subpart E. All laboratories that are located within the State of New York and hold valid CLEP permits are CLIA-exempt for all specialties and subspecialties until March 26, 2027.

## **III. Collection of Information Requirements**

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

The Acting Administrator of the Centers for Medicare & Medicaid Services (CMS), Elizabeth Richter, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

**Dated:** March 25, 2021.

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**Lynette Wilson,**

Federal Register Liaison,

Centers for Medicare & Medicaid Services.